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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

ISABELLA, DAVID J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,840

Applicant(s)

MILLER ET AL.

Examiner

DAVID J ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 48-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47 and 70-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Election/Restrictions

Applicant's election of claims 1-47,70-72 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 48-69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8,13-19,26,27,31,70-72 are rejected under 35 U.S.C. 102(e) as being anticipated by Darouiche (6475434).

Darouiche discloses providing an implantable medical device with at least one biocompatible matrix polymer region and bioactive agents comprising an antimicrobial agent and a biofilm synthesis inhibitor.

Claims 2 and 3, the biofilm inhibitor may be present on one surface of the device or over multiple surfaces of the device.

Claim 4, see rejection to claim 1.

Claim 5, see column 5, lines 57+, the device being implants (ie devices designed for long term implantation).

Claim 6, see column 6, lines 5+.

Claim 7, see columns 5, lines 66+.

Claim 8, see column 6, lines 1+.

Claims 13 and 14, see column 17, lines 43+.

Claims 15-19, see any examples 1-3 of Darouiche.

Claims 26,27,31 see laminates of Darouiche.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9,10,11,12,26-42, 70-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darouiche (6475434) as applied to claim1 above, and further in view of Helmus, et al (5569463) or Zaffaroni et al (4036227).

While Darouiche discloses a general listing of materials that may be used as the base matrix, including ethylene and acetate compositions, the use of ethylene vinylacetate is not specifically disclosed. Helmus, et al and Zaffaroni et al teaches a

listing of materials that may be used as a base matrix for medical devices including ethylene and acetate compositions including ethylene vinylacetate composition and degradable materials including polylactic and polyglycolic acids. If not inherent in Darouiche, the use of ethylene vinyl acetate as a base matrix for medical devices would have been obvious from the teachings of Helmus, et al or Zaffaroni et al based upon the use of equivalent materials depending upon the engineering constraints of the particular application of the device.

Claims 26-33,70,71 see Zaffaroni, et al. The use of a barrier layer to control the release of the active agents is taught by Zaffaroni, et al. The annulus shape see the appropriate figures of Zaffaroni,et al. The composition of the matrix polymer region, see Darouiche as modified by either of Helmus or Zaffaroni et al.

Claims 34-42, see disclosure of intended devices in each of Darouiche, Helmus and Zaffaroni et al.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darouiche as applied to claim 1 above, and further in view of Braden (5468787).

Darouiche does not disclose the use of a medical device with a base matrix having radioopacifying agent incorporated therewith. Braden teaches a medical device with a base polymer matrix with biocidal agents having radioopacifying agent incorporated therewith to provide contrast of the device for surgical positional verification by the surgeon. To complex radioopacifying agent, barium sulfate with the base matrix of Darouiche to to provide contrast of the device for surgical positional

verification by the surgeon would have been obvious to one with ordinary skill in the art from the teaching of Braden.

Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darouiche as applied to claim 1 above, and further in view of Capelli (5607683).

Darouiche does not disclose the use of a medical device with a base matrix having therapeutic agent incorporated therewith. Capelli teaches a medical device with a base polymer matrix with biocidal agents having therapeutic agent incorporated therewith to prevent infections in the wounds when employing the device in vivo. To complex a therapeutic agent with the base matrix of Darouiche to prevent infection at the wound site would have been obvious to one with ordinary skill in the art from the teaching of Capelli.

Claims 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Darouiche as modified by the secondary references as applied to claim 35 above, and further in view of Redkar (6482830).

While the specific medical device of a pancreatic stent is not specifically disclosed by Darouiche as modified, Redkar teaches the use of a catheter or a stent for treatment to the pancreas wherein the device comprises a bicarbonate buffering agent. The use of a stent of Darouiche as modified by the secondary references to treat the pancreas wherein the stent comprises buffering agents would have been obvious to one

with ordinary skill in the art from the teachings of Redkar in order to obviate the needs of an indwelling catheter thereby reducing the risk of infections.

Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Darouiche, et al in view of Helmus, et al, Zaffaroni et al and Braden.

Darouiche discloses providing an implantable medical device with at least one biocompatible matrix polymer region and bioactive agents comprising an antimicrobial agent and a biofilm synthesis inhibitor. While Darouiche discloses a general listing of materials that may be used as the base matrix, including ethylene and acetate compositions, the use of ethylene vinylacetate is not specifically disclosed. Helmus, et al and Zaffaroni et al teaches a listing of materials that may be used as a base matrix for medical devices including ethylene and acetate compositions including ethylene vinylacetate composition and degradable materials including polylactic and polyglycolic acids. If not inherent in Darouiche, the use of ethylene vinyl acetate as a base matrix for medical devices would have been obvious from the teachings of Helmus, et al or Zaffaroni et al based upon the use of equivalent materials depending upon the engineering constraints of the particular application of the device. Darouiche does not disclose the use of a medical device with a base matrix having radioopacifying agent incorporated therewith. Braden teaches a medical device with a base polymer matrix with biocidal agents having radioopacifying agent incorporated therewith to provide contrast of the device for surgical positional verification by the surgeon. To complex radioopacifying agent, barium sulfate with the base matrix of Darouiche to provide

contrast of the device for surgical positional verification by the surgeon would have been obvious to one with ordinary skill in the art from the teaching of Braden.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
1/12/04